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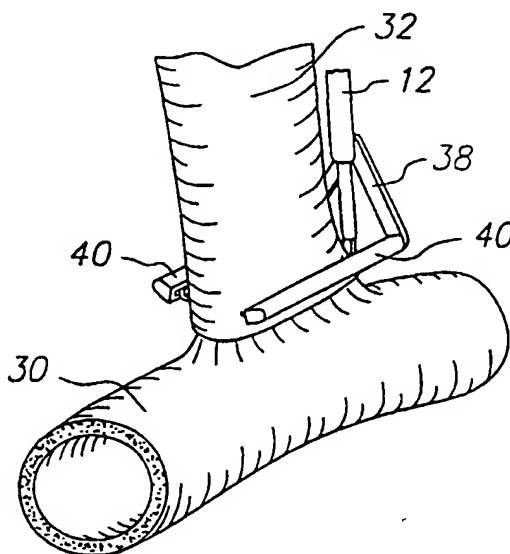
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(75) Inventors/Applicants (for US only): VARGAS, Jaime
(21) International Application Number: PCT/US00/20418 [US/US]; 879 Clara Drive, Palo Alto, CA 94303 (US).
HENDRICKSEN, Michael [US/US]; No. 4. 612 Cambridge Avenue, Menlo Park, CA 94025 (US). YENCHO,
(22) International Filing Date: 27 July 2000 (27.07.2000) Stephen, A. [US/US]; 320 Linfield Drive, Menlo Park,
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(54) Title: ANASTOMOSIS SYSTEM AND METHOD FOR CONTROLLING A TISSUE SITE



(57) Abstract: An anastomosis system and method uses an anvil to control and support a tissue site during an anastomosis procedure. The anvil is particularly useful for supporting a wall of a coronary artery during attachment of a graft vessel to the coronary artery because the wall of the coronary artery is very thin, difficult to grasp, and susceptible to tearing. In one method, the anvil is inserted into a pressurized or unpressurized target vessel and is pulled against an inner wall of the target vessel causing tenting of the thin tissue of the vessel wall. A graft vessel is then advanced to the anastomosis site and an end of the graft vessel is positioned adjacent and exterior of the target vessel. Staples are inserted through the tissue of the graft vessel and the target vessel by pivoting the arms of a staple holder towards the anvil. When the ends of the staples engage staple bending features on the anvil, the ends of the staples bend over securing the graft vessel and target vessel together. After stapling is complete, an incision is formed in the wall of the target vessel to allow blood flow between the target vessel and the graft vessel.

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ANASTOMOSIS SYSTEM AND METHOD FOR CONTROLLING A TISSUE SITE

BACKGROUND OF THE INVENTION

5 Field of the Invention

The invention relates to an anastomosis system and method, and more particularly, the invention relates to an anastomosis system for controlling a tissue site during an anastomosis procedure.

Brief Description of the Related Art

10 Vascular anastomosis is a procedure by which two blood vessels within a patient are surgically joined together. Vascular anastomosis is performed during treatment of a variety of conditions including coronary artery disease, diseases of the great and peripheral vessels, organ transplantation, and trauma. In coronary artery disease (CAD) an occlusion or stenosis in a coronary artery interferes with
15 blood flow to the heart muscle. Treatment of CAD involves the grafting of a vessel in the form of a prosthesis or harvested artery or vein to reroute blood flow around the occlusion and restore adequate blood flow to the heart muscle. This treatment is known as coronary artery bypass grafting (CABG).

In the conventional CABG, a large incision is made in the chest and the
20 sternum is sawed in half to allow access to the heart. In addition, a heart lung machine is used to circulate the patient's blood so that the heart can be stopped and the anastomosis can be performed. In order to minimize the trauma to the patient induced by conventional CABG, less invasive techniques have been developed in which the surgery is performed through small incisions in the patients chest with
25 the aid of visualizing scopes. Less invasive CABG can be performed on a beating or stopped heart and thus may avoid the need for cardiopulmonary bypass.

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In both conventional and less invasive CABG procedures, the surgeon has to suture one end of the graft vessel to the coronary artery and the other end of the graft vessel to a blood supplying vein or artery, such as the aorta. The suturing process is a time consuming and difficult procedure requiring a high level of surgical skill. In order to perform the suturing of the graft to a target vessel such as the coronary artery or the blood supplying artery the surgeon generally has an assistant hold the edges of the incision in the target vessel while the surgeon takes small stitches as close as possible to the edges of the incision. This suturing requires a high degree of precision and is quite time consuming. In addition, during conventional CABG procedures blood flow at the anastomosis site is stopped during suturing. This prevents bleeding from the incision site but also prevents blood from reaching a portion of the heart muscle served by the vessel.

Accordingly, it would be desirable to provide a vascular anastomosis system which allows the tissue at the anastomosis site to be controlled during suturing or other connection of the graft and target vessels. It would also be desirable to provide a vascular anastomosis system which allows the connection of a graft vessel to a target vessel prior to making an incision in the target vessel which allows blood flow between the target vessel and the graft vessel.

SUMMARY OF THE INVENTION

The present invention relates to an anastomosis system and method for controlling a blood vessel tissue site during an anastomosis procedure. The anastomosis system and method may be used on a pressurized vessel or on an unpressurized vessel. The anastomosis may be accomplished with sutures, staples, or other securing members.

In accordance with one aspect of the present invention, a method of controlling a tissue site during an anastomosis procedure includes the steps of inserting an anvil into a pressurized vessel at an intended anastomosis site,

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supporting a wall of the pressurized vessel at the intended anastomosis site with the anvil positioned adjacent an interior of the wall, performing anastomosis, and removing the anvil.

In accordance with another aspect of the invention, a method of controlling
5 a tissue site during an anastomosis procedure includes the steps of inserting an anvil into a target vessel at an intended anastomosis site, supporting a wall of the target vessel at the intended anastomosis site with the anvil positioned adjacent an interior of the wall, performing anastomosis between a graft vessel and the target vessel, and making an incision in the wall of the target vessel to allow blood flow
10 between the graft vessel and the target vessel.

In accordance with an additional aspect of the present invention, an anastomosis system for connecting a graft vessel to a target vessel includes an elongated anvil having substantially parallel staple bending features for bending the ends of staples, at least one staple with staple ends configured to be received by
15 the staple bending features, and a staple holder for holding the at least one staple while puncturing tissue.

In accordance with a further aspect of the invention, an anvil for use in performing anastomosis between a graft vessel and a target vessel includes a handle, and an elongated anvil arm extending from the handle. The anvil arm has
20 substantially parallel staple bending grooves or recesses for bending the ends of anastomosis staples. The elongated anvil arm is configured to be inserted into the target vessel beside an anastomosis site through a small incision which allows pressurization of the vessel to be maintained.

According to another aspect of the invention, a stapling system for use in
25 performing anastomosis between a graft vessel and a target vessel includes a plurality of staples having ends configured to be inserted through tissue and bent over to secure the tissue, an expandable backbone supporting the plurality of

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staples for insertion. The backbone has an expandable configuration allowing a spacing between the plurality of staples to be changed.

In accordance with an additional aspect of the invention, a stapling system for use in performing anastomosis between a graft vessel and a target vessel includes a plurality of staples having ends configured to be inserted through tissue and bent over to secure the tissue, a staple strip holding the plurality of staples in a spaced arrangement for insertion into the tissue as a row of staples, and a frangible portion provided between each of the plurality of staples and the staple strip allowing the staples to be separated from the staple strip after insertion.

10

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described in greater detail with reference to the preferred embodiments illustrated in the accompanying drawings, in which like elements bear like reference numerals, and wherein:

15 FIG. 1 is a perspective view of an anvil and a plurality of staples according to a first aspect of the present invention;

FIG. 2 is a perspective view of the anvil of FIG. 1 being inserted into a target vessel;

20 FIG. 3 is a perspective view of the anvil tenting a wall of a target vessel for an anastomosis procedure;

FIG. 4 is a perspective view of a graft vessel placed adjacent an exterior of the tented target vessel for the anastomosis procedure;

FIG. 5 is a perspective view of the staples being applied to the graft vessel and the target vessel during an anastomosis procedure;

25 FIG. 6 is a perspective view of the completed anastomosis according to the first aspect of the present invention;

FIG. 7 is a perspective view of a staple supported on a staple holding strip;

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FIG. 8 is a side view of the staple and staple holding strip of FIG. 7 when the ends of the staple have been bent by contact with an anvil;

FIG. 9 is a perspective view of an anvil and staple according to another aspect of the present invention;

5 FIGS. 10A and 10B are is a side views of a plurality of staples supported on two embodiments of expandable staple holding strips;

FIG. 11 is a perspective view of a portion of an anvil having a movable cutting device;

FIG. 12 is a side view of an anvil having an external cutting device;

10 FIGS. 12A and 12B are side views of a portion of an anvil and two cutting devices which snap onto the anvil;

FIG. 13 is a side view of a portion of an anvil with an extendable cutting device;

15 FIG. 14 is a side view of the anvil of FIG. 13 with the cutting device extended;

FIG. 15 is a side view of a portion of an anvil with an alternative embodiment of an extendable cutting device;

FIG. 16 is a side view of the anvil of FIG. 15 with the cutting device extended;

20 FIG. 17 is a perspective view of an anvil according to a second aspect of the invention being inserted into a target vessel;

FIG. 18 is a perspective view of the anvil of FIG. 17 positioning inside a target vessel and a clamp being advanced to clamp the wall of the target vessel between the anvil and the clamp;

25 FIG. 19 is a perspective view of a graft vessel being advanced to the target vessel with a continuous anastomosis staple while the anastomosis site on the target vessel is controlled by the anvil and clamp;

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FIGS. 20-22 are side cross sectional views of the steps of performing the anastomosis with the continuous anastomosis staple shown in FIG. 19;

FIG. 23 is a perspective view of the completed anastomosis performed as shown in FIGS. 19-22;

5 FIGS. 24-27 are perspective views of the steps of an alternative anvil and clamp system for controlling an anastomosis site and forming an incision through the clamped tissue of the target vessel;

FIG. 28 is a perspective view of a system for controlling a tissue site and performing anastomosis according to the present invention;

10 FIG. 29 is a cross sectional view taken along line C-C of FIG. 28, showing a first step of the anastomosis procedure;

FIG. 30 is a cross sectional view taken along line C-C of FIG. 28, showing a second step of the anastomosis procedure;

15 FIG. 31 is a cross sectional view taken along line C-C of FIG. 28, showing a third step of the anastomosis procedure;

FIG. 32 is a perspective view of an anvil according to another aspect of the present invention for use with sutures; and

FIG. 33 is a perspective view of the anvil of FIG. 32 positioned within a target vessel and used to locate a plurality of suture at an anastomosis site.

20

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The anastomosis system and method according to the present invention uses an anvil to control and support a tissue site during an anastomosis procedure. The anvil is particularly useful for supporting a wall of a coronary artery during
25 attachment of a graft vessel to the coronary artery because the wall of the coronary artery is very thin, difficult to grasp, and susceptible to tearing. Although the present invention is particularly useful for controlling very thin tissues such as the

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walls of the coronary arteries, the anvil may also be used for controlling other tissue sites.

As shown in FIG. 1, an anvil 10 according to one aspect of the present invention includes a handle 12 and an anvil arm 14 extending substantially perpendicular from the handle. The anvil arm 14 is provided with several staple bending features 16 on opposite sides of the anvil arm 14. In the anvil shown in FIG. 1, the staple bending features 16 each include a plurality of recesses 20 which receive the ends of staples and cause the staple ends to bend over.

Also shown in FIG. 1 are a plurality of staples 22 connected to a staple holding strip 24. The staples 22 are preferably U-shaped staples which are arranged in a spaced apart parallel configuration such that the staples all lie in a single plane.

The anvil arm 14 has a sharp distal end 28 for puncturing the tissue of a target vessel to insert the anvil arm 14 into the target vessel. As illustrated in FIG. 2, the anvil arm 14 is inserted into a pressurized or unpressurized target vessel 30 by puncturing the target vessel with the distal end 28 of the anvil arm. The hole which is formed in the wall of the target vessel 30 by the anvil arm 14 is small enough to prevent significant bleeding through the puncture site. The hole is preferably less than 2 mm, and more preferably less than 1 mm in width.

Once the anvil arm 14 has been inserted into the target vessel 30, the anvil arm 14 is pulled against an inner wall of the target vessel causing tenting of the thin tissue of the vessel wall as illustrated in FIG. 3. This tenting of the vessel wall provides control over the anastomosis site during an anastomosis procedure which is described with respect to FIGS. 4-6.

As shown in FIG. 4, a graft vessel 32 is advanced to the anastomosis site and an end 34 of the graft vessel is positioned adjacent and exterior of the target vessel 30 at the anastomosis site. The tented portion of the target vessel 30 is inside the graft vessel in the step of FIG. 4. As shown in FIG. 5, a staple holder

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38 is provided having two arms 40 which are pivotally connected to the handle 12 of the anvil. Alternatively, the pivoting arms 40 of the staple holder may be connected to a separate device. A staple holder 38 may be used to hold individual staples or preferably, the staple holder will hold the staple holding strips 24 as
5 shown in FIG. 1. The staples 22 are inserted through the tissue of the graft vessel 32 and the target vessel 30 by pivoting the arms 40 of the staple holder 38 towards the anvil arm 14. When the ends of the staples 22 engage the staple bending features 16 on the anvil arm 14, the ends of the staples are bent over securing the graft vessel 32 and target vessel 30 together. Once the staple ends are bent over,
10 the staples 22 are released from the staple holding strip 24 or the staple holder 38 resulting in spaced apart staples securing the graft vessel 32 and the target vessel 30 together as shown in FIG. 6.

After stapling is complete, an incision is formed in the wall of the target vessel 30 to allow blood flow between the target vessel and the graft vessel 32.
15 Some examples of methods and devices for forming the incision will be described in further detail below. After completion of the anastomosis, the anvil arm 14 is withdrawn from the target vessel 30 between adjacent staples 22. The withdrawal of the anvil arm 14 leaves a gap which is approximately the same as the spacing between adjacent staples. Accordingly, no blood leakage occurs at the location
20 where the anvil arm has been withdrawn.

FIG. 6 illustrates a completed anastomosis between a target vessel 30 and a graft vessel 32 with a plurality of staples 22. A spacing between the staples 22 is preferably approximately 1 to 4 mm. This spacing is similar to the spacing between sutures in a conventional sutured anastomosis.

25 One example of an anvil arm 14 according to the present invention has a height and a width of about 2 mm or less, preferably about 1 mm or less, and a length of about 2 to 15 mm, preferably 5 to 12 mm. The length of the anvil will

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vary depending on the diameter of the graft vessel selected. Preferably, a length to width ratio of the anvil arm 14 is between 2:1 and 15:1.

The preferred staples 22 for use in the present invention have widths of about 0.2 - 3 mm, preferably about 2 mm or less and leg lengths of about 0.2 - 3
5 mm.

FIGS. 7 and 8 illustrate one example of a staple 22 connected to a staple holding strip 24. This staple 22 includes barbed staple ends 52 extending from the front portion of the staple and a C-shaped portion 54 extending from a rear of the staple for connecting the staple to the staple holding strip 24. The staple holding
10 strip 24 includes a plurality of protrusions 56 for receiving the staples 22. The C-shaped portion 54 of the staple is received around one of the protrusions 56 and is preferably secured in place at one or more locations such as by welds 58 or other frangible portions. As shown in FIG. 8, when the staple holding strip 24 is advanced toward the anvil arm 14, the barbed staple ends 52 are received in the
15 recesses 20 in the anvil arm causing the barbed staple ends to bend towards one another. At the same time that the barbed staple ends 52 bend over, or after the bending of the staple ends, the staple is detached from the staple holding strip 24. The staple 22 may be detached from the staple holding strip 24 by the action of bending the barbed staple ends, by bending a frangible connection between the
20 staple holding strip and the staples to separate the staples, or any other known separation methods, such as melting of a connection between the staple and the staple holding strip.

FIG. 9 illustrates an alternative embodiment of a staple 22a having inwardly curved barbed staple ends 52a. These inwardly curved barbed staple
25 ends do not require the curved staple bending surfaces of the recesses 20 to bend the ends of the staples over. As shown in FIG. 9, the staple bending features 16a on the anvil arm 14a may be formed as a longitudinal groove along the anvil arm.

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When the curved ends 52a of the staple 22a are received in the groove 16a of the anvil arm 14a, the ends bend inward to secure the tissue with the staple.

FIG. 10A illustrates a plurality of staples 22a positioned on an expandable staple holding strip called an expandable backbone 66. The expandable backbone 66 includes a plurality of elements 68 which are interconnected by one or more expanding members 70. Each of the backbone elements 68 is provided with a connecting diamond member 72 which is connected to one of the staples 22a. According to the embodiment illustrated in FIG. 10A, the staples 22a are each connected to the diamond members 72 by a thin connecting section 74. The expandable backbone 66 allows the spacing between the staples 22a to be adjusted for the particular anastomosis to be performed. Preferably the backbone 66 allows expansion of the distance between staples from a distance of approximately 0.1 mm to a distance of approximately 1 to 4 mm, i.e., expansion of up to 40 times the original spacing.

The expanding backbone 66 also includes two openings 76 at opposite ends which may be engaged by pins on an anastomosis system or staple holder. The opening 76 allow the backbone to be easily expanded by relative motion of holding pins.

The connecting diamond members 72 are configured to collapse inwardly toward the backbone when the staples 22a engage the staple bending surfaces 16a of the anvil. The collapsing of the diamond members 72 forces the staples 22a to separate from the diamond members at the connecting sections 74.

FIG. 10B illustrates an alternative embodiment of staples 22a and a backbone 66. In the embodiment of FIG. 10B, the staples 22a are each connected to the associated backbone elements 68 at two connecting sections 74.

FIG. 11 shows a portion of an anvil arm 14 with a movable cutting device 44. The cutting device 44 includes a base 46 and a blade 48. The base 46 of the cutting device 44 is positioned in a longitudinal groove 50 in the anvil arm 14.

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After the anvil arm 14 has been inserted into the target vessel, the cutting device 44 may be moved longitudinally along the anvil arm to form an incision in the target vessel.

FIGS. 12, 12A, and 12B illustrate external cutting devices which are advanced down onto the anvil 14 after the anastomosis procedure and cut an incision in the target vessel from an exterior of the target vessel as the anvil is withdrawn. As shown in FIG. 12, a knife 62 is positioned on a knife arm which is movable along the handle 12 of the anvil. The knife 62 is moved downward until the knife engages a recess 65 in the anvil 14. As the anvil 14 is withdrawn from the anastomosis site, the knife 62 forms the incision in the target vessel.

FIGS. 12A and 12B illustrate two alternative embodiments of the knife 62 which snap onto a corresponding engagement surface 65 of the anvil 14 so that the knife and anvil are secured together for formation of the incision during removal of the anvil from the anastomosis site.

FIGS. 13 - 16 illustrate two variations of extendable cutting devices for making an incision in the target vessel while drawing the anvil arm 14 from the target vessel. FIG. 13 illustrates an anvil arm 14b having a blade 78 connected to a blade support 80. When the blade support 80 is pulled in the direction of the arrow A with respect to the anvil arm 14b, the blade 78 moves from a forwardly extending position shown in FIG. 13 to an upwardly extending position shown in FIG. 14. The blade 78 in the forwardly extending position may be used to form the small opening to insert the anvil arm 14 into the target vessel. After an anastomosis has been performed, the blade 78 is moved to an upwardly angled or a vertical position in which the blade is used to form an incision in the target vessel as the anvil arm 14b is removed from the target vessel.

FIGS. 15 and 16 illustrate an alternative embodiment of an anvil arm 14c having a blade 84 and a blade support 86. While the anvil arm 14c is being inserted into the target vessel and during the anastomosis procedure, the blade 84

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is positioned in a recess 88 in the anvil arm. The blade 84 may be moved from the position of FIG. 15 to the extended position of FIG. 16 by moving the blade support 86 in the direction of the arrow B with respect to the anvil arm.

Alternatively, the blade 84 may be extended automatically upon withdrawal of the anvil arm 14 when a blade tip 90 catches on an interior surface of the target vessel wall during withdrawal of the anvil arm.

The examples of extendable cutting devices for use with the anvil according to the present invention which are shown in FIGS. 13 - 16, are merely shown as examples of the type of cutting devices which may be used for making the incision. Once these cutting devices or blades have been extended from the anvil arm, they may be fixed to perform cutting as the anvil arm is removed from the target vessel or the blades may be movable along the anvil arm to make an incision prior to removal of the anvil arm from the target vessel.

FIGS. 17 - 23 illustrate an alternative embodiment of an anvil 100 which is used with a clamp 102 for controlling an incision site during an anastomosis procedure. As shown in FIGS. 17 and 18, the anvil 100 includes an anvil arm 104 and a handle 106. The clamp 102 is slidable on the handle 106 to clamp the tissue of the target vessel 30 between the clamp 102 and the anvil arm 104. As in the embodiments discussed previously, the anvil arm 104 includes two rows of staple bending features 108 in the form of recesses positioned in two parallel rows along a top surface of the anvil. The clamp 102 has a central opening 110. Once the tissue of the target vessel wall has been trapped between the clamp 102 and the anvil arm 104, an incision may be made through the target vessel wall and the edges of the incision are controlled by the combination of the anvil and the clamp.

As shown in FIG. 19, a continuous anastomosis staple device 114 may be used to connect the graft vessel 32 to the target vessel 30 at the anastomosis site. The staple device 114 as shown in FIG. 19 includes a plurality of linkages forming a tubular configuration and a plurality of staple ends extending from the linkages.

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FIGS. 20 - 22 illustrate how the staple ends 116 of the staple device 114 are positioned in the end of the graft vessel 32 and are inserted through the incision 118 in the target vessel and bent over by contact with the staple bending features 108 of the anvil. As shown in FIG. 22, the opposite ends 120 of the staple device 114 are folded over to complete the anastomosis. FIG. 23 illustrates a completed anastomosis performed according to the steps illustrated in FIGS. 19-22.

FIGS. 24 - 27 illustrate an alternative embodiment of an anvil having a 14d cutting wire 124 for forming the incision in the wall of the target vessel 30. The cutting wire 124 of FIGS. 24 - 27 may be used to form an incision either before or after performing an anastomosis procedure. For forming the incision after the anastomosis procedure, a clamp 126 is used to trap the tissue at the anastomosis site between the clamp and the anvil prior to performing the incision as shown in FIGS. 26 and 27.

FIG. 28 shows a system 140 for controlling a tissue site and performing anastomosis according to the present invention. For purposes of clarity, the staple holder and staples have been omitted from FIG. 28. The system 140 includes an anvil 142, a cutter 144, and a graft vessel holder 146 all mounted on a handle 148. The anvil 142 is mounted on the handle 148 and connected to an actuator 150 which allows the anvil to be moved downward against the bias of a spring inside the handle. The cutter 144 may be spring biased or fixed and is positioned on the handle 148 directly above the anvil 142. The graft vessel holder 146 includes two fixed arms 152 and two movable arms 154. The two movable arms 154 are connected to a second actuator 156 on the handle 148. Depression of the second actuator 156 against the bias of a spring within the handle causes the movable arms 154 to be moved downward away from the fixed arms to receive portions of a graft vessel between the movable and fixed arms.

The operation of the system 140 of FIG. 28 is shown in the cross sectional views of FIGS. 29-31. As shown in FIG. 29, an end of a graft vessel 32 is split so

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that the two halves of the graft vessel can be held by the graft vessel holder 146. In order to load the graft vessel into the system 140, the first actuator 150 and the second actuator 156 are depressed to move the anvil 142 and the movable arms 154 downward. The split graft vessel 32 is then inserted between the fixed and
5 movable arms 152, 154 and the second actuator 156 is released to trap the ends of the graft vessel, as shown in FIG. 30. The anvil 142 is then inserted into the target vessel 30 as described above with respect to the various other anvil embodiments.

Once the anvil has been inserted in the target vessel 30 as shown in FIG.
10 30, the actuator 150 is released to allow the anvil to move upward to tent the wall of the target vessel. FIG. 31 illustrates the tented target vessel 30 positioned adjacent the split and trapped graft vessel 32 in a position for performing anastomosis. The staple holders 38 are then advanced in the direction of the arrows D toward opposite sides of the anvil to staple the graft vessel and target
15 vessel together. Preferably, the staple holders hold a staple strip with an expandable backbone as shown in FIGS. 10A and 10B. The holders 38 may be provided with movable pins which allow a spacing between the staples to be adjusted depending on a size of the graft vessel used. Once the staples have been placed the anvil 142 is removed and the cutter 144 makes an incision in the target
20 vessel during removal of the anvil.

FIGS. 32 and 33 illustrate the use of an anvil 130 for controlling the tissue at an anastomosis site. The anvil 130 includes a longitudinal slot 132 extending through the anvil for application of a plurality of conventional sutures at the anastomosis site. According to this method, the anvil 130 is inserted into the
25 target vessel 30 and pulled against the interior wall of the target vessel, tenting the target vessel as shown in FIG. 33. Sutures 134 are then passed through the slot 132 in the anvil 130 and through the tissue of the target vessel wall on opposite sides of the anvil. Once the sutures are placed as shown in FIG. 33, an incision is

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made in the target vessel along a center of the anvil 130. A center portion of each of the sutures 34 is then pulled out through the incision in the target vessel and cut so that an even row of sutures is provided along each of the sides of the incision.

This system eliminates the tedious procedure of placing each individual suture very close to the edge of the incision in the very thin and flexible target vessel wall.

Each of the sutures 134 are connected to a graft vessel in a conventional manner completing the anastomosis. The anvil as shown in FIGS. 32 and 33 allows quick and easy placement of a plurality of sutures in a very even manner close to the edge of the incision. For example, the sutures of a conventional anastomosis are generally within about one millimeter of the edge of the incision and are preferably within 0.5 millimeters of the edge of the incision.

The invention has been described as including staple bending features provided on the anvil and staples provided at an exterior of the tissue. According to an alternative embodiment of the invention, the staples and/or staple holding strips may be positioned on the anvil and an exterior member with staple bending features may be moved toward the anvil to bend the ends of the staples and secure the graft and target vessels together.

While the invention has been described in detail with reference to the preferred embodiments thereof, it will be apparent to one skilled in the art that various changes and modifications can be made and equivalents employed, without departing from the present invention.

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WHAT IS CLAIMED IS:

1. An anastomosis system for connecting a graft vessel to a target vessel, the anastomosis system comprising:
 - an anastomosis device for securing a graft vessel to a target vessel
 - 5 at a plurality of connection points; and
 - a tissue supporting anvil for supporting tissue of the target vessel from an interior of the target vessel while securing the graft vessel to the target vessel with the anastomosis device, the tissue supporting anvil having a tissue penetrating tip at a first end, an anvil handle at a second end, and an elongated
 - 10 tissue supporting surface extending longitudinally from the tissue penetrating tip to the anvil handle, the elongated tissue supporting surface supporting the tissue of the target vessel at the plurality of tissue connection points during connection.
2. The anastomosis system of Claim 1, wherein the anastomosis device is a staple holder for holding a plurality of staples while puncturing tissue of a
- 15 graft vessel and a target vessel with the staples.
3. The anastomosis system of Claim 2, further comprising a plurality of staples positioned in the staple holder and arranged to connect the graft vessel to the target vessel.
4. The anastomosis system of Claim 3, wherein the plurality of staples
- 20 are mounted on two staple holding backbones which are received in the staple holder.
5. The anastomosis system of Claim 4, wherein a frangible portion is provided between the plurality of staples and the staple holding backbones.

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6. The anastomosis system of Claim 2, wherein the tissue supporting anvil includes substantially parallel staple bending features.

7. The anastomosis system of Claim 6, wherein the substantially parallel staple bending features are formed on opposite sides of the anvil.

5 8. The anastomosis system of Claim 6, wherein the substantially parallel staple bending features are formed on a top side of the anvil.

9. The anastomosis system of Claim 1, wherein the anastomosis device includes two movable arms which move toward the anvil to connect the graft vessel to the target vessel at the connection points.

10 10. The anastomosis system of Claim 9, wherein the two movable arms are pivotally connected to the anvil handle.

11. The anastomosis system of Claim 1, wherein the tissue penetrating tip of the anvil is configured to pierce the tissue of the target vessel.

12. The anastomosis system of Claim 1, wherein the anastomosis device
15 secures the graft vessel to the target vessel at the plurality of connection points simultaneously.

13. The anastomosis system of Claim 1, wherein the anastomosis device and anvil are configured to hold the graft vessel and the target vessel together at all of the connection points during the anastomosis.

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14. The anastomosis system of Claim 1, further comprising a cutting member provided on the anvil for cutting an incision in the target vessel after the anastomosis has been performed.

15. The anastomosis system of Claim 14, wherein the cutting member is a knife movable along the elongated tissue supporting surface of the anvil.

16. The anastomosis system of Claim 14, wherein the cutting member includes a cutting wire which is pulled through a slot.

17. The anastomosis system of Claim 14, wherein the cutting member is a knife which cuts the target vessel tissue as the anvil is withdrawn from the target vessel.

18. The anastomosis system of Claim 1, wherein the anvil has a width of 2 mm or less such that the anvil can be withdrawn from the target vessel between adjacent connection points without leakage.

19. The anastomosis system of Claim 1, wherein the anvil has a width of 1 mm or less such that the anvil can be withdrawn from the target vessel between adjacent connection points without leakage.

20. A stapling system for use in performing anastomosis between a graft vessel and a target vessel, the stapling system comprising:
a plurality of staples having ends configured to be inserted through tissue of the graft and target vessels and bent over to secure the tissue together;
and

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a backbone supporting the plurality of staples for insertion, the staples connected to the backbone by frangible connecting portions allowing the staples to be disconnected from the backbone upon insertion into the tissue.

21. The stapling system of Claim 20, wherein the staples are
5 substantially U-shaped.

22. The stapling system of Claim 20, wherein each of the staples is connected to the backbone by at least two frangible connections.

23. The stapling system of Claim 20, wherein the backbone and staples are formed from a single sheet of material.

10 24. A method of controlling a tissue site during an anastomosis procedure, the method comprising:

inserting an anvil into a pressurized vessel at an intended anastomosis site;

15 supporting a wall of the pressurized vessel at the intended anastomosis site with the anvil positioned adjacent an interior of the wall;

performing anastomosis; and

removing the anvil.

25. The method of Claim 24, further comprising a step of forming an incision in the wall of the pressurized vessel after the step of performing the
20 anastomosis to allow blood flow between the pressurized vessel and a graft vessel.

26. The method of Claim 25, wherein the incision extends along the anvil from a puncture in the vessel where the anvil was inserted.

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27. The method of Claim 25, wherein the incision is made while removing the anvil.

28. The method of Claim 25, wherein the incision is made before removing the anvil.

5 29. The method of Claim 24, wherein the step of performing anastomosis includes inserting staples through a graft vessel and a target vessel and bending ends of the staples against the anvil.

30. The method of Claim 24, wherein the step of performing anastomosis includes suturing a graft vessel and the pressurized vessel together.

10 31. The method of Claim 24, further comprising a step of clamping a wall of the pressurized vessel between the anvil and a clamp, and forming an incision in the wall of the pressurized vessel before the step of performing the anastomosis.

15 32. The method of Claim 24, wherein the anvil is an elongated member having substantially parallel features for supporting tissue of the pressurized vessel while puncturing the tissue during anastomosis.

33. A method of controlling a tissue site during an anastomosis procedure, the method comprising:

20 inserting an anvil into a target vessel at an intended anastomosis site;

 supporting a wall of the target vessel at the intended anastomosis site with the anvil positioned adjacent an interior of the wall;

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performing anastomosis between a graft vessel and the target vessel;
and
making an incision in the wall of the target vessel to allow blood
flow between the graft vessel and the target vessel.

5 34. The method of Claim 33, wherein the anastomosis is performed on
a pressurized target vessel.

35. The method of Claim 33, wherein the incision is made while
removing the anvil from the target vessel.

10 36. The method of Claim 33, wherein the incision is made before
removing the anvil from the target vessel.

37. An anastomosis system for connecting a graft vessel to a target
vessel, the anastomosis system comprising:

an elongated anvil having substantially parallel staple bending
features for bending the ends of staples;

15 at least one staple with staple ends configured to be received by the
staple bending features; and

a staple holder for holding the at least one staple while puncturing
tissue.

20 38. The anastomosis system of Claim 37, wherein the two substantially
parallel staple bending features are formed along opposite sides of the anvil arm.

39. The anastomosis system of Claim 37, wherein the at least one staple
comprises a plurality of U-shaped staples.

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40. The anastomosis system of Claim 39, wherein the plurality of U-shaped staples are mounted on two staple holding strips which are received in the staple holder.

5 41. The anastomosis system of Claim 40, wherein a frangible portion is provided between the plurality of U-shaped staples and the staple holding strips allowing the staples to be separated from the staple strips.

42. The anastomosis system according to Claim 40, wherein the staple holder includes two arms movably connected to a handle, each of the arms configured to receive one of the staple holding strips.

10 43. The anastomosis system of Claim 37, wherein the two substantially parallel staple bending features are both formed on a top side of the anvil.

44. The anastomosis system of Claim 37, wherein the at least one staple comprises a staple body and a plurality of tissue puncturing staple ends extending from the staple body and configured to be received by the substantially parallel
15 staple bending features.

45. The anastomosis system of Claim 44, wherein the staple body is formed from a plurality of struts.

46. The anastomosis system of Claim 37, further comprising a clamp which is movable with respect to the anvil arm to trap tissue between the anvil and
20 the clamp.

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47. The anastomosis system of Claim 46, wherein the clamp is elongated in shape to correspond to the elongated shape of the anvil and has an opening for receiving the at least one staple.

48. The anastomosis system of Claim 37, wherein the substantially
5 parallel staple bending features each include a plurality of recesses.

49. The anastomosis system of Claim 37, wherein the substantially parallel staple bending features are grooves extending along the elongated anvil.

50. A method of performing anastomosis comprising:
providing an elongated anvil having two substantially parallel rows
10 of staple bending features bending the ends of staples;
inserting the elongated anvil through the wall of a target blood vessel and positioning the elongated anvil along an interior of the target blood vessel wall;
positioning a graft vessel adjacent an exterior of the target blood
15 vessel wall;
inserting the ends of at least one staple through the graft vessel and the target vessel;
bending the ends of the at least one staple by advancing the ends against the staple bending features of the elongated anvil to secure the graft vessel
20 to the target vessel; and
making an opening in the target vessel to allow blood to flow between the target vessel and the graft vessel.

51. The method of Claim 50, wherein the opening is made in the target vessel after the graft vessel has been secured to the target vessel.

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52. The method of Claim 50, wherein edges of the opening in the target vessel are held by a clamp and the opening is made in the target vessel before the graft vessel has been secured to the target vessel.

53. An anvil for use in performing anastomosis between a graft vessel
5 and a target vessel, the anvil comprising:
a handle; and
an elongated anvil arm extending from the handle, the anvil arm
having substantially parallel staple bending grooves or recesses for bending the
ends of anastomosis staples, wherein the elongated anvil arm is configured to be
10 inserted into the target vessel at an intended anastomosis site through a small
incision which allows pressurization of the vessel to be maintained.

54. A stapling system for use in performing anastomosis between a
graft vessel and a target vessel, the stapling system comprising:
a plurality of staples having ends configured to be inserted through
15 tissue and bent over to secure the tissue; and
an expandable backbone supporting the plurality of staples for
insertion, the backbone having an expandable configuration allowing a spacing
between the plurality of staples to be changed.

55. The stapling system of Claim 54, wherein the staples are connected
20 to the backbone by frangible portions.

56. The stapling system of Claim 54, wherein the expandable backbone
is formed as a single piece.

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57. A method of performing anastomosis comprising:
- providing a plurality of interconnected staples;
 - selecting a graft vessel;
 - expanding a spacing between the interconnected staples to match a
- 5 circumference of the selected graft vessel; and
- connecting the graft vessel to a target vessel with the staples.

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FIG. 1

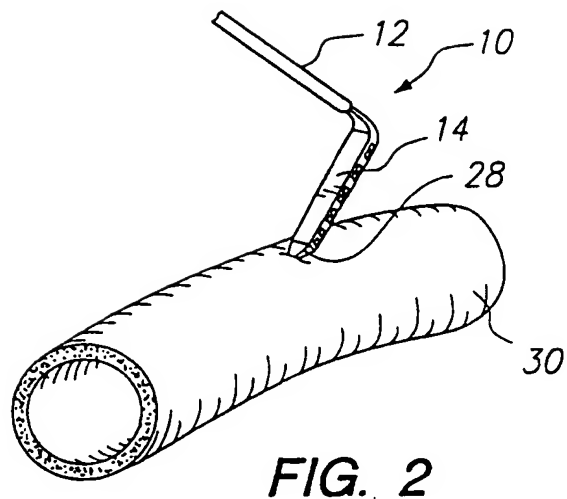
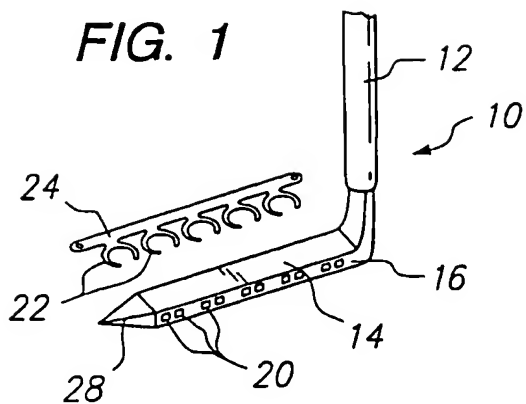


FIG. 2

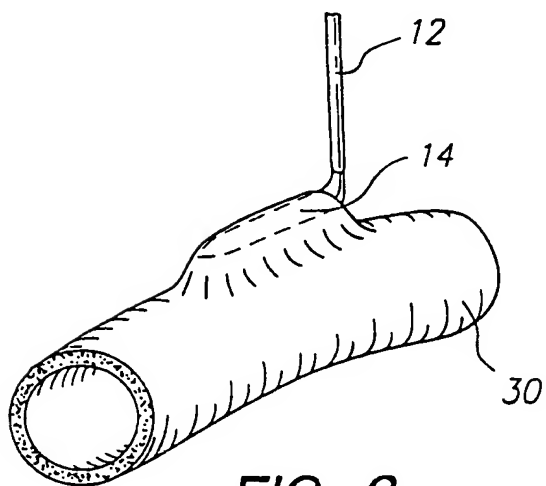


FIG. 3

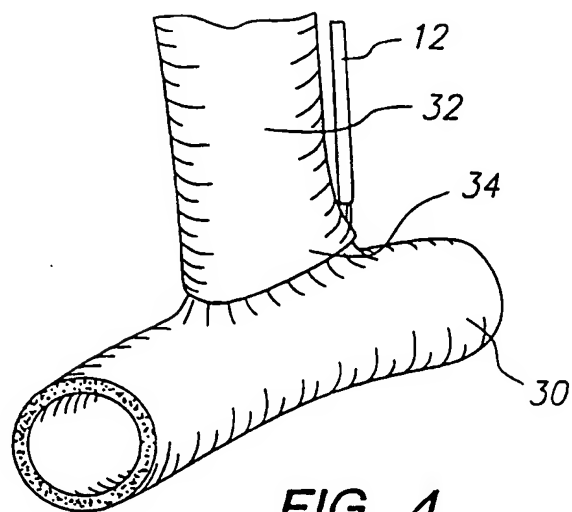
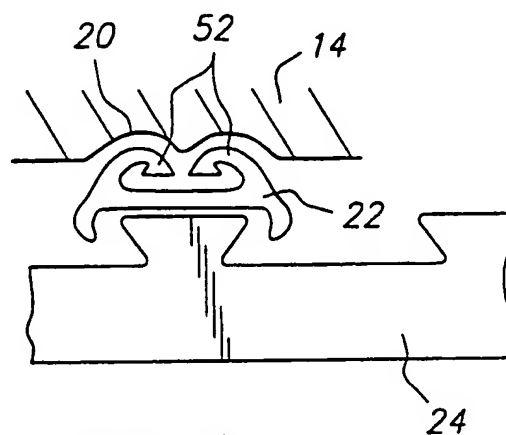
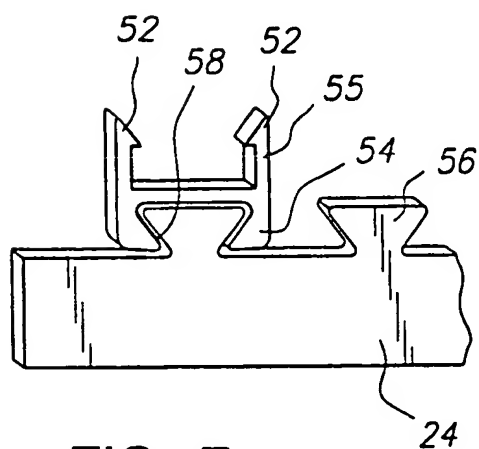
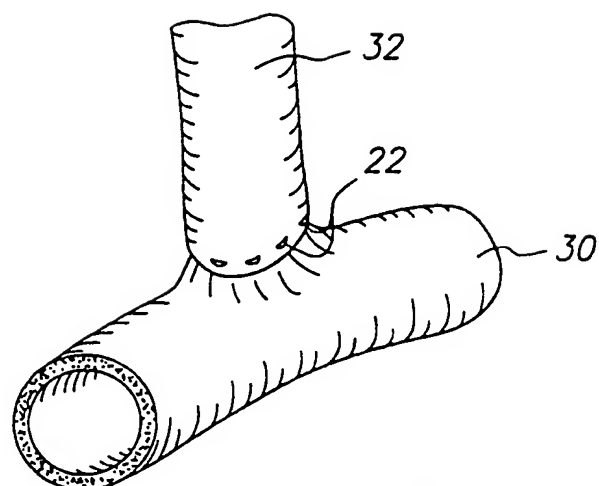
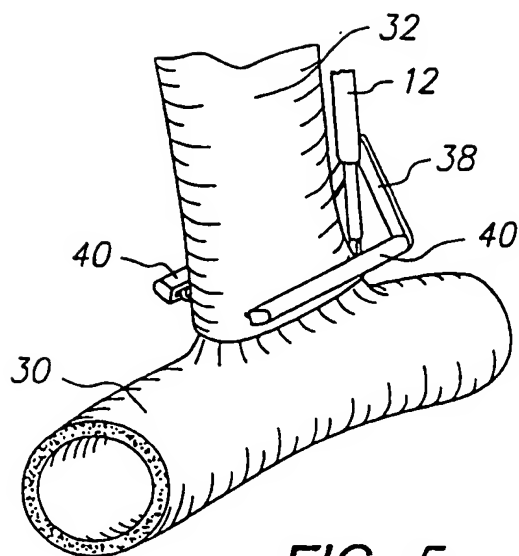


FIG. 4

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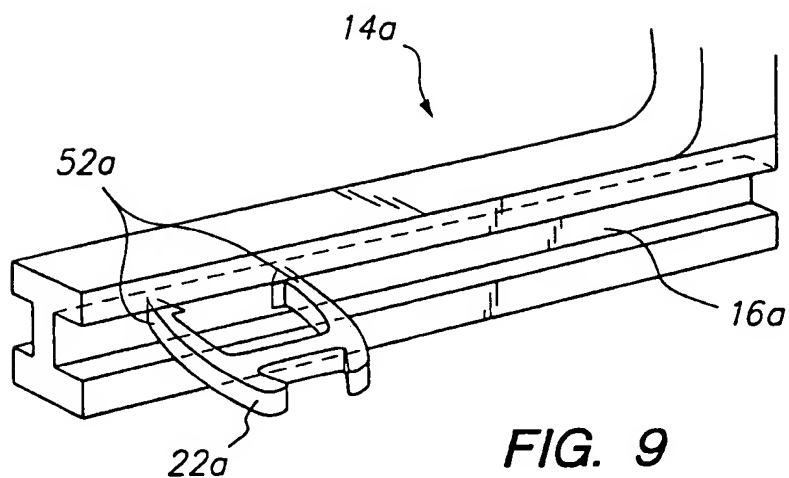


FIG. 9

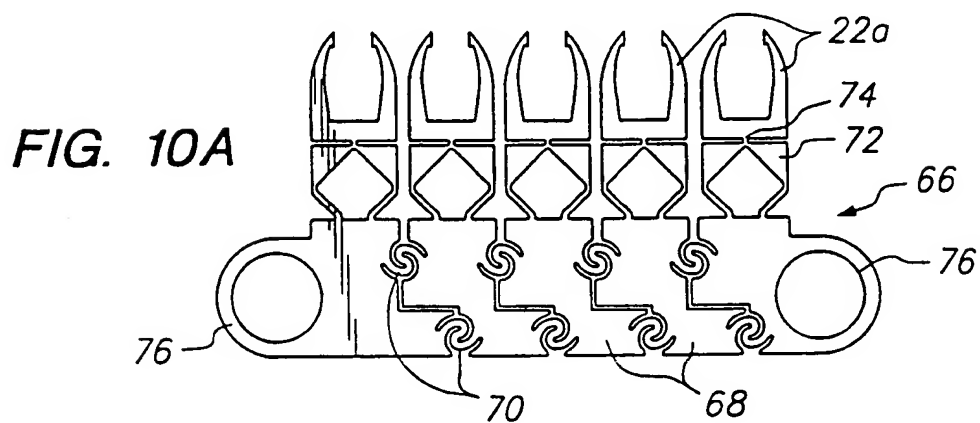


FIG. 10A

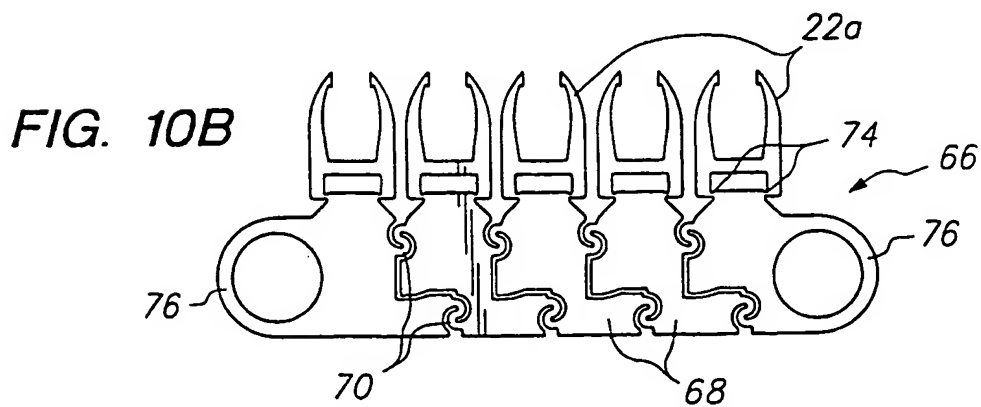
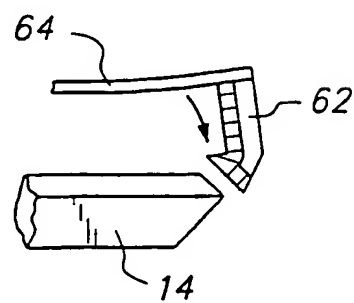
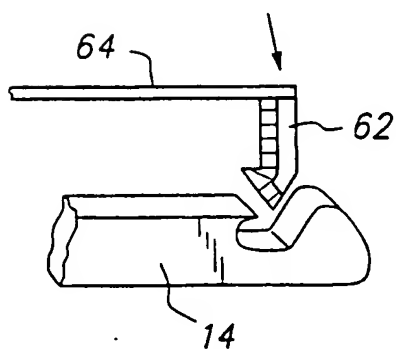
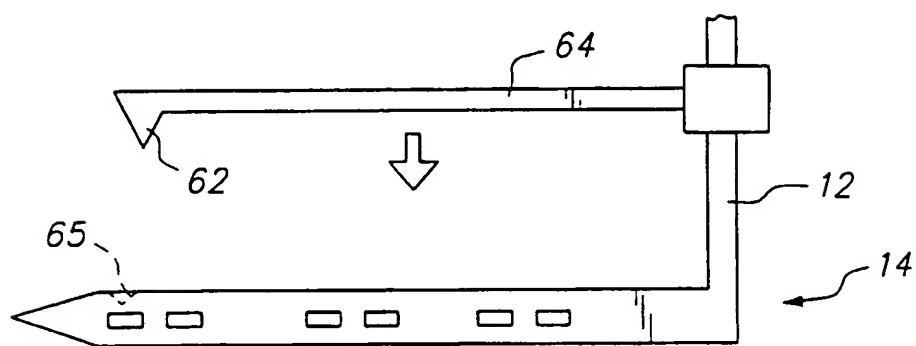
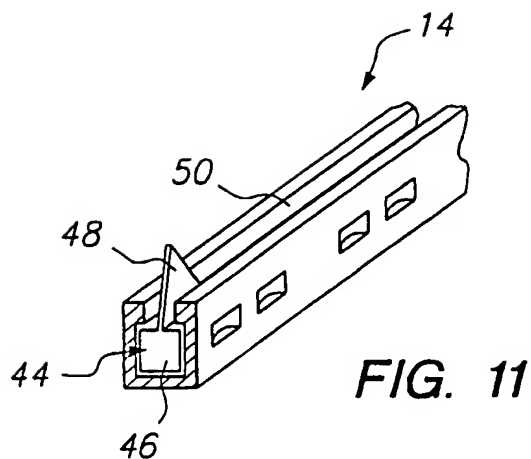
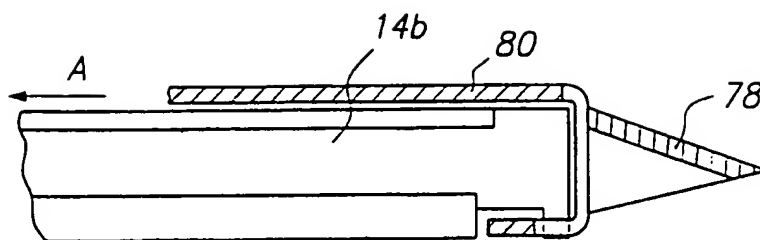
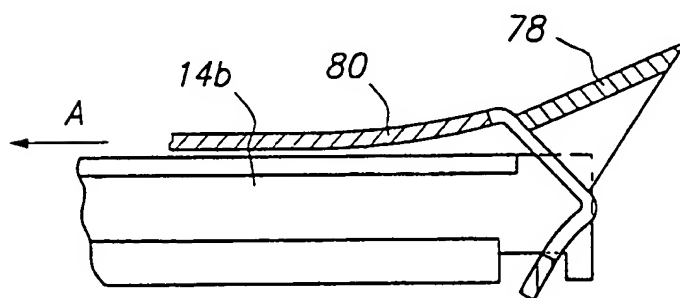
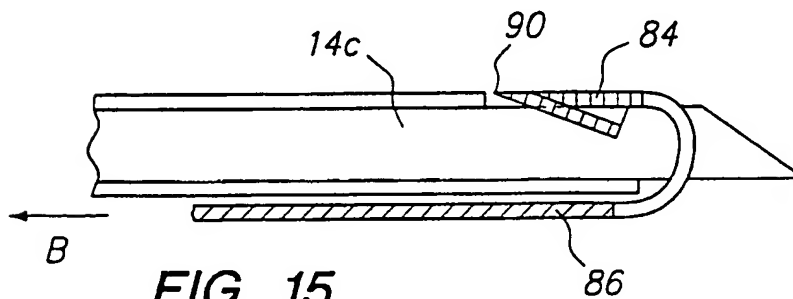
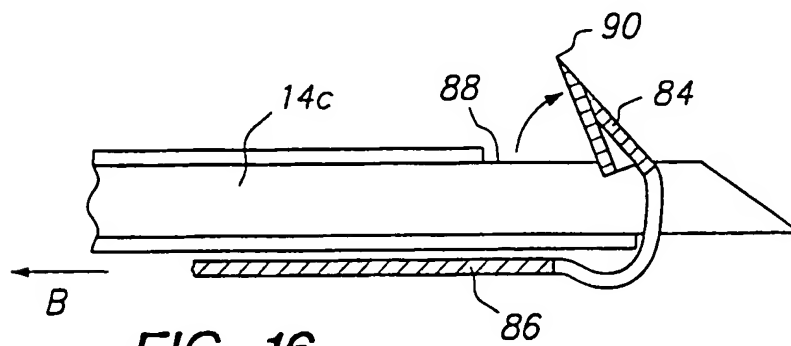


FIG. 10B

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**FIG. 13****FIG. 14****FIG. 15****FIG. 16**

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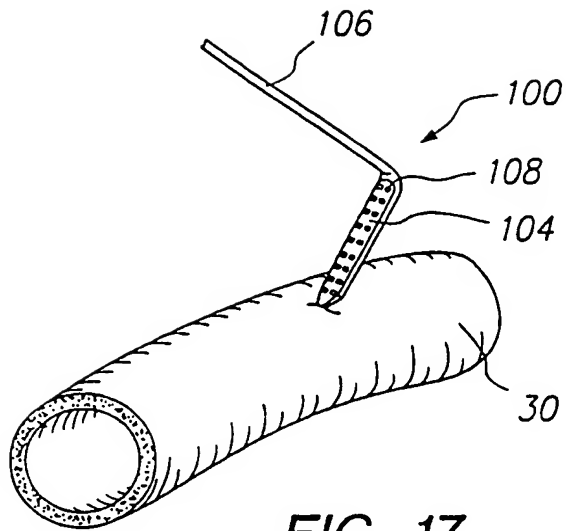


FIG. 17

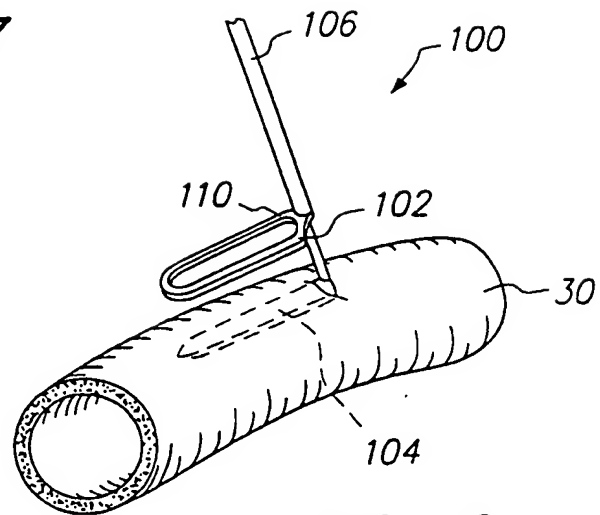


FIG. 18

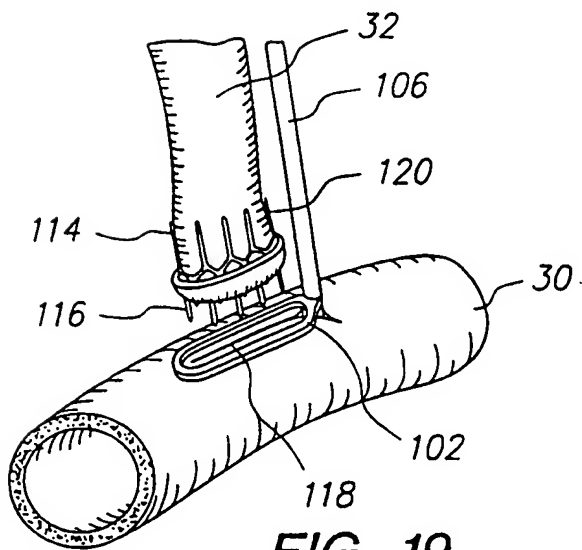


FIG. 19

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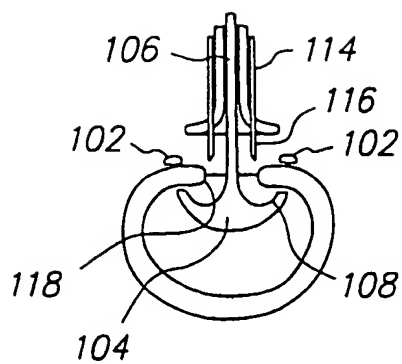


FIG. 20

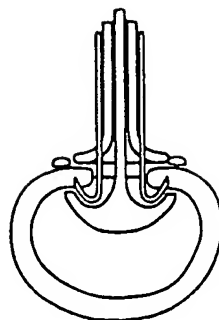


FIG. 21

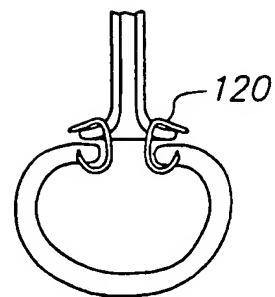


FIG. 22

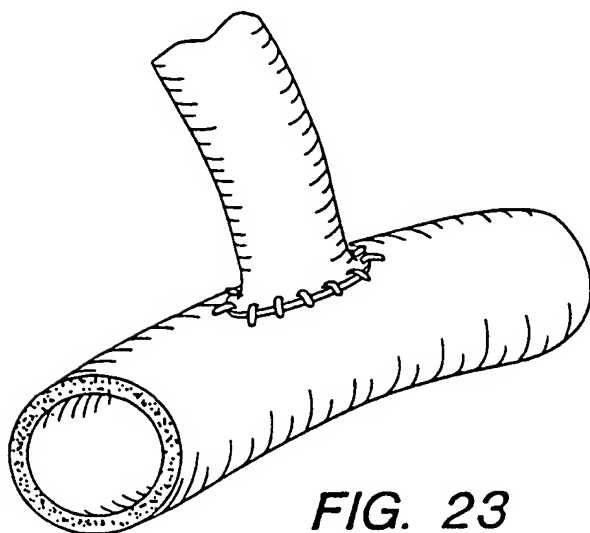


FIG. 23

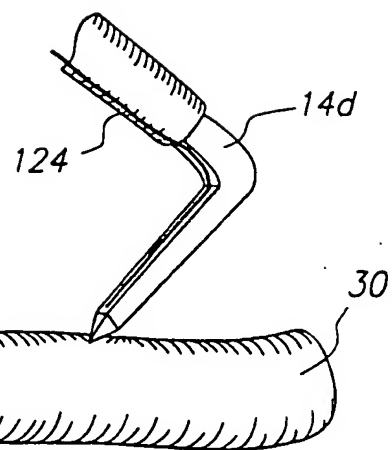


FIG. 24

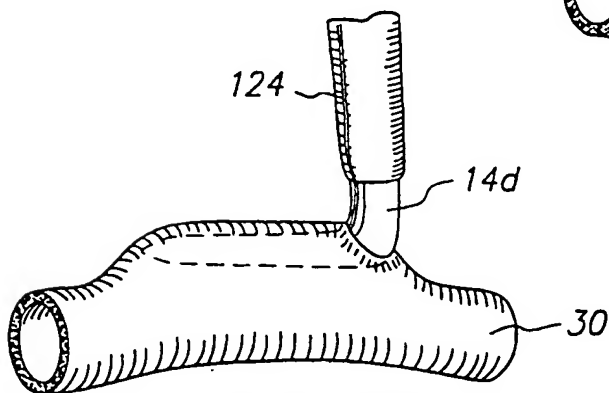
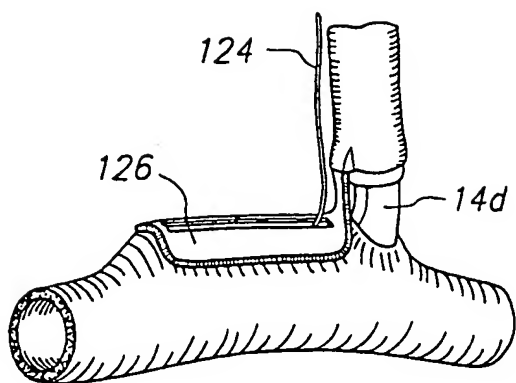
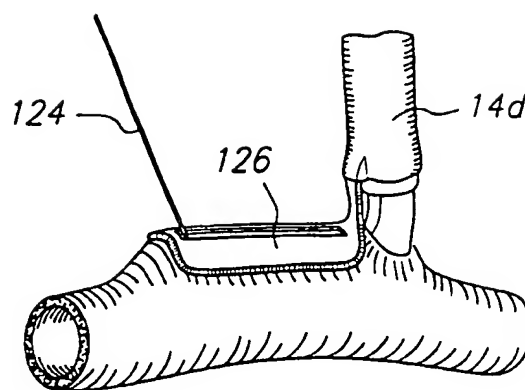
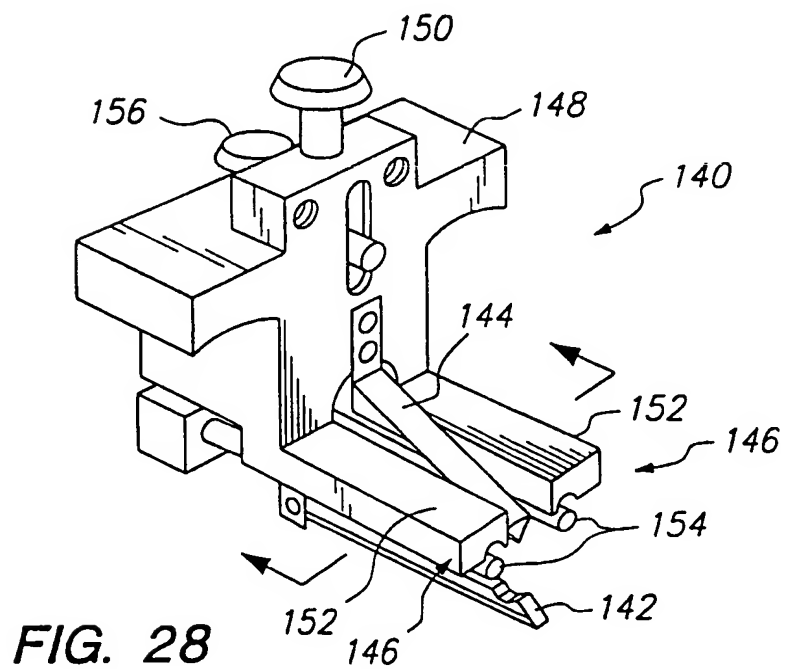


FIG. 25

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**FIG. 26****FIG. 27****FIG. 28**

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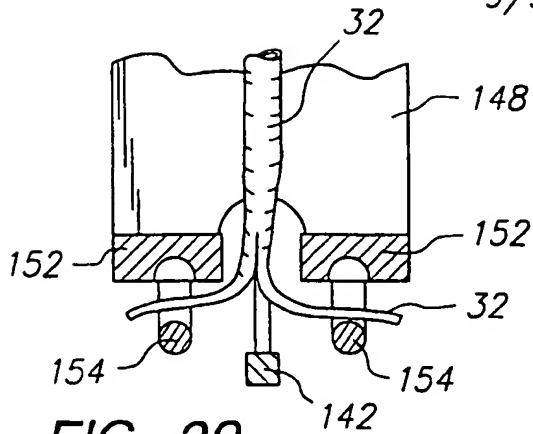


FIG. 29

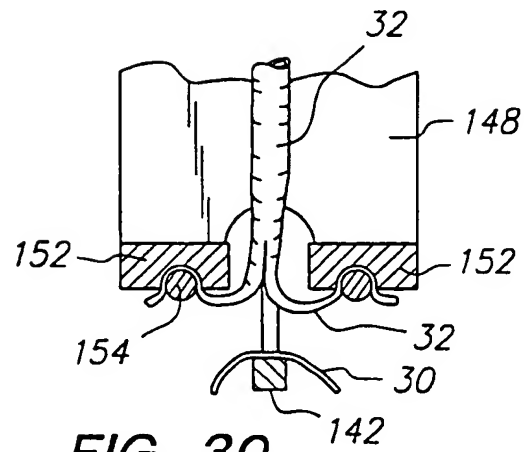


FIG. 30

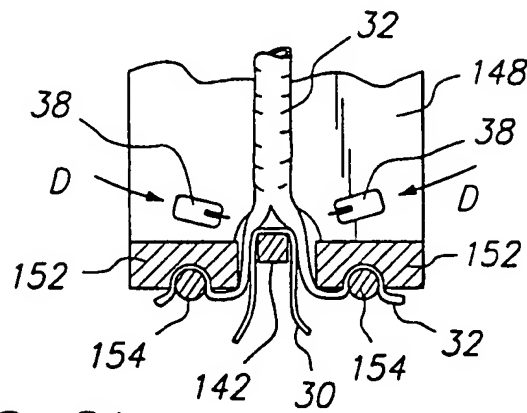


FIG. 31

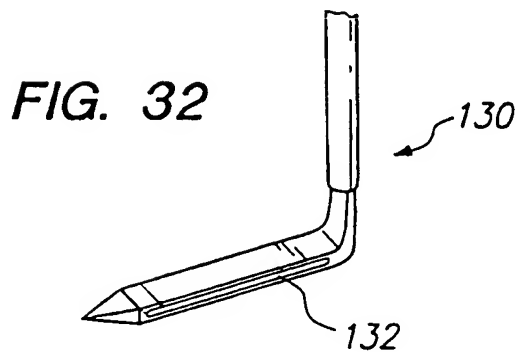


FIG. 32

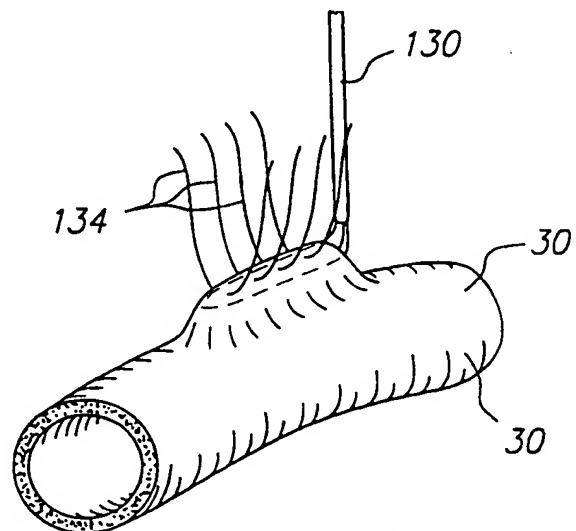


FIG. 33